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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,521	09/01/2006	Hiroharu Kawahara	125192.00501	1684
7590 Pepper Hamilton 500 Grant Street, 50th Floor Pittsburgh, PA 15219			EXAMINER KIM, ALEXANDER D	
			ART UNIT	PAPER NUMBER
			1656	
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			10/03/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,521	<b>Applicant(s)</b> KAWAHARA, HIROHARU	
	<b>Examiner</b> ALEXANDER D. KIM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (mailed on 03/19/2008), Applicants filed a response and amendment received on 06/17/2008. Said amendment cancelled Claims 1-7 and 19; amended Claims 20 and 21.

Claims 8-18 and 20-21 are pending in the instant Office action. Claims 8-18 are withdrawn as non-elected inventions.

Claims 20-21 will be examined herein.

### ***Objections to the Specification***

2. The specification discloses that the cell strains SC. 01MFP and SC. 02MFP are established from the RPMI8226 and KMS.12BM, respectively (see page 8, middle). The "KMS. 12BM" should be ---KMS-12BM---, as recited on page 6.

It is clear that SC. 01MFP and SC. 02MFP cell strain is originate from the RPMI8226 and the KMS.12BM, respectively. However, because the applicants fail to disclose any method step of preparing SC. 01MFP and SC. 02MFP; the instant specification fails to disclose any structural difference between the established cell strain and the original strains. Thus it is unclear how SC. 01MFP and SC. 02MFP were "established from RPMI8226 and KMS.12BM". For examination purposes, absent evidence to the contrary, the SC. 01MFP and the SC. 02MFP are considered to be a culture of RPMI8226 cell and KMS.12BM cell, respectively.

Appropriate clarification and/or correction is required.

***Withdrawn-Claim Objections***

3. The previous objection to the Claims 1-7 and 20-21, for Claim 1 (Claims 2-6 and 20-21 dependent therefrom) reciting "0.1 to mg per 1,000,000 cells", is withdrawn by virtue of Applicants' cancelling Claims 1-7.

4. The previous objection to the Claim 7, for reciting "10 .mu.g/day" is withdrawn by virtue of Applicants' cancelling Claim 7.

***Claim Objections***

5. Claims 20 and 21 recite "SC-02MFP" or "SC-01MFP". It should be ---SC. 02MFP--- or ---SC. 01MFP---, accordingly, to be constant with the terms used in the specification (see page 8, for example).

***Withdrawn-Claim Rejections - 35 USC § 112***

6. The previous rejection of Claims 20-21 under 35 U.S.C. 112, first paragraph, enabling deposit, as failing to comply with the enablement requirement is withdrawn by virtue of declaration with the signature of attorney of record filed on 06/17/2008.

7. The previous rejection of Claims 1-7 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancelling Claims 1-7.

8. The previous rejection of Claims 1-7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancelling Claims 1-7.

***Withdrawn-Claim Rejections - 35 USC § 102***

9. The previous rejection of Claims 1-7 under 35 U.S.C. 102(b) as being anticipated by Kawahara et al. (1999, Human Antibodies, Volume 9, pages 83-87) is withdrawn by virtue of Applicants' cancelling Claims 1-7.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Pene et al. (Oncogene, 2002, Volume 21, pages 6587-6597). The instant rejection is necessitated by Applicants' amendment.

Claim 20 is drawn to the cell culture SC-01MFP deposited as Accession Number FERM BP-10077.

As noted in the objection to the specification, it is clear that SC. 01MFP and SC. 02MFP cell strain is originated from the RPMI8226 and the KMS.12BM, respectively. However, because the applicants failed to disclose any method step of preparing SC. 01MFP and SC. 02MFP; the instant specification fails to disclose any structural

difference between the established cells strain and the original strain. Thus, based on broad and reasonable interpretation and in view of specification, the cell SC-01MPF Claim 20 is interpreted to be a culture of RPMI8226 cell, for example.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Pene et al. teach the cell "RPMI8226" which is considered to anticipate SC-01MFP, absent evidence to the contrary.

11. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Hata et al. (Clin Exp Immunol, 1994, Volume 94, pages 370-375). Instant rejection is necessitated by Applicants' amendment.

Claim 21 is drawn to the cell culture SC-01MFP deposited as Accession Number FERM BP-10077.

As noted in the objection to the specification, it is clear that SC. 01MFP and SC. 02MFP cell strain is originated from the RPMI8226 and the KMS.12BM, respectively. However, because the applicants failed to disclose any method step of preparing SC. 01MFP and SC. 02MFP; the instant specification failed to disclose any structural difference between the established cells strain and the original strain. Thus, based on

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broad and reasonable interpretation and in view of specification, the cell SC-01MPF

Claim 21 is interpreted to be a culture of KMS.12BM cell, for example.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Hata et al. teach the "Myeloma cell line KMS12BM" (see middle of left column, page 371, Materials and Methods) which is considered to anticipate SC-01MPF, absent evidence to the contrary.

### ***Conclusion***

12. Claims 20 and 21 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/Alexander D Kim/  
Examiner, Art Unit 1656

/Richard G Hutson, Ph.D./  
Primary Examiner, Art Unit 1652